UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

Children's Health Defense, *et al.*, Plaintiffs, v. Food & Drug Administration, *et al.*, Defendants.	Case No. 6:22-cv-00093-ADA-DTG

Defendants' Motion to Dismiss the First Amended Complaint for Lack of Subject-Matter Jurisdiction and Failure to State a Claim

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INTRODUCTION

Plaintiffs oppose the U.S. Food and Drug Administration's ("FDA") issuance of emergency use authorizations for administration of the Pfizer-BioNTech ("the Pfizer EUA") and Moderna ("the Moderna EUA") COVID-19 vaccines to children aged 6 months through 11 years. But no matter how fervent their policy disagreement—about the prospects of "pharmapocalypse" or any other issue—it does not amount to an Article III case or controversy. On this basis, their Amended Complaint should be dismissed.

Despite adding three plaintiffs and pages of allegations, Plaintiffs have done nothing to address the fundamental standing defects that prompted dismissal of their first Complaint. No individual plaintiff has shown any actual or imminent threat of harm to self or child that is fairly traceable to the EUAs' existence. And Children's Health Defense ("CHD") still cannot establish representational standing through an injured member or organizational standing via injury to itself.

Were any plaintiff to possess standing, sovereign immunity also deprives this Court of jurisdiction. Both claims in the Amended Complaint depend on the Administrative Procedure Act's ("APA") waiver of sovereign immunity. But FDA's issuance of an EUA ranks among the class of agency actions that Congress exempted from review under the APA. Absent an applicable waiver of sovereign immunity, Plaintiffs' challenge cannot proceed.

Finally, even if Plaintiffs could establish this Court's subject-matter jurisdiction, they still have not plausibly alleged any claim upon which relief can be granted. Plaintiffs' APA and Declaratory Judgment Act claims are unsupported by statute or precedent, and their factual challenges are refuted by the face of FDA's documents that are attached to or incorporated by reference in the Amended Complaint. These claims fail as a matter of law.

BACKGROUND

I. FDA's issuance of the Pfizer and Moderna EUAs

Ordinarily, a manufacturer of a biological product, including a vaccine, may market the product "only if the FDA has licensed it" pursuant to the Public Health Service Act. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017); *see* 42 U.S.C. § 262(a), (i)(1). But in times of "an actual or potential emergency," Congress empowered the Secretary of Health and Human Services ("the Secretary") to authorize the introduction into interstate commerce of biological products (and other FDA-regulated products) "intended for use" in responding to the emergency. 21 U.S.C. § 360bbb-3(a)(1).

The Secretary first determines that a "public health emergency . . . affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad." *Id.* § 360bbb-3(b)(1)(C). The Secretary then may declare that circumstances exist justifying the marketing of FDA-regulated products "intended for use" in responding to the emergency. *Id.* § 360bbb-3(a)(1), (b). Following those declarations, FDA may issue an EUA for a vaccine intended for use in diagnosing, treating, or preventing the disease or condition that created the emergency. *Id.* § 360bbb-3(c). Congress expressly committed all these decisions to agency discretion. *Id.* § 360bbb-3(i).

On February 4, 2020, the Secretary determined, under 21 U.S.C. § 360bbb-3(b)(1)(C), that a public health emergency existed involving the virus SARS-CoV-2, which causes COVID-19. 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). On March 27, 2020, the Secretary declared that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." 85 Fed. Reg. 18,250, 18,250–51 (Apr. 1, 2020). FDA subsequently issued EUAs for COVID-19 vaccines manufactured by Pfizer-BioNTech and ModernaTX, Inc. *See* 86 Fed. Reg. 5200 (Jan. 19, 2021) (initial Pfizer and Moderna EUAs).

On October 29, 2021, FDA revised the Pfizer EUA to authorize administration of the Pfizer vaccine to individuals 5 through 11 years of age. ECF No. 26-1, at 106, 110. Then on June 17, 2022, FDA expanded the Pfizer EUA to include administration to individuals aged 6 months through 4 years. *Id.* at 107. Both times, the agency concluded that it was "reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in" those age groups, and "based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine" for those groups. *Id.* at 110, 114. FDA also drew the same conclusions for the Moderna EUA on June 17, 2022, to authorize administration to individuals 6 months through 17 years. ECF No. 26-2, at 86.

The Pfizer and Moderna EUAs require vaccination providers to make available an approved "Fact Sheet for Recipients and Caregivers," in hardcopy or online. ECF No. 26-1, at 123; ECF No. 26-2, at 94. These Fact Sheets, which are publicly available on FDA's website, inform parents and other caregivers that "there is an option to accept or refuse receiving the vaccine." Pfizer Fact Sheet for 6 Months Through 4 Years, at 5 (June 28, 2022), https://perma.cc/M3V7-RF2Z.[1] A decision "not to receive" the vaccine "will not change [the] child's standard medical care." *Id.*; *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) ("individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product").

II. CHD's opposition to COVID-19 vaccines, and this lawsuit

CHD is a New Jersey-based advocacy group that opposes the COVID-19 vaccines. *See* Am. Compl., ECF No. 26, at ¶ 8. In May 2021, CHD petitioned FDA to "refrain from licensing COVID-19 vaccines and to revoke EUAs for the three existing COVID-19

[1] *See also* Pfizer Fact Sheet for 5 Through 11 Years, at 5 (June 28, 2022), https://perma.cc/E7US-7JU4; Moderna Fact Sheet for 6 Months Through 5 Years, at 4 (June 17, 2022), https://perma.cc/4G3N-Q5DX; Moderna Fact Sheet for 6 Through 11 Years, at 4 (June 17, 2022), https://perma.cc/V826-EBUX.

vaccines." *Id.* ¶ 146. Three months later, FDA provided a detailed response of more than 50 pages, ultimately denying CHD's petition because it lacked "facts demonstrating any reasonable grounds for the requested action." *See id.* ¶ 148; ECF No. 26-3, at 63.

CHD also has pursued (unsuccessfully) its objections to COVID-19 vaccines through the courts. *See Children's Health Def. v. FDA*, No. 21-6203, 2022 WL 2704554, at *1 (6th Cir. July 12, 2022) (affirming dismissal for lack of standing in challenge to "FDA's licensure of Pfizer's Comirnaty COVID-19 vaccine and FDA's reauthorization of the" Pfizer EUA); *Children's Health Def. v. Rutgers State Univ. of N.J.*, No. CV2115333ZNQTJB, 2021 WL 4398743, at *1, 8 (D.N.J. Sept. 27, 2021) (denying CHD's preliminary injunction motion against university COVID-19 vaccination policy); *see also Aviles v. Blasio*, No. 20 CIV. 9829 (PGG), 2021 WL 796033, at *16 (S.D.N.Y. Mar. 2, 2021) (dismissing CHD, for lack of standing, from challenge to New York City schools' COVID-19 policy).

On January 24, 2022, CHD returned to court and, alongside two individuals, filed this suit against FDA and Robert M. Califf, M.D., Commissioner of Food and Drugs. *See* Compl., ECF No. 1. On May 21, 2022, this Court granted Defendants' motion to dismiss, finding Plaintiffs lacked standing. On July 1, 2022, CHD filed a First Amended Complaint, challenging FDA's issuance of the Moderna and Pfizer EUAs for children aged 6 months through 11 years. *See* Am. Compl. ¶¶ 33–34. The Amended Complaint alleges one APA claim and another for declaratory relief. *See* Am. Compl. ¶¶ 213–250. Defendants renew their motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) and (b)(6) for lack of subject-matter jurisdiction and failure to state a claim.

LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) challenges the Court's subject-matter jurisdiction, which must "be established as a threshold matter." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998). The Court "presume[s]" to

"lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotations omitted)); *see Brownback v. King*, 141 S. Ct. 740, 749 (2021) (plaintiff "must plausibly allege all jurisdictional elements"). If the burden is not met, the Court "must dismiss the action." Fed. R. Civ. P. 12(h)(3).

"To survive a motion to dismiss" under Rule 12(b)(6), Plaintiffs' "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Court need not accept as true "conclusory statements" or "legal conclusions." *Iqbal*, 556 U.S. at 678–79. The complaint must "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Iqbal*, 556 U.S. at 678, and "raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555. "[I]f as a matter of law 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations,' a claim must be dismissed, without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one." *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

ARGUMENT

I. This Court still lacks subject-matter jurisdiction

The same two bedrock jurisdictional precepts that required dismissal of the original Complaint apply as forcefully to the Amended Complaint. First, "[u]nder Article III, federal courts do not possess a roving commission to publicly opine on every legal question" and "do not exercise general legal oversight of the Legislative and Executive Branches." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). Litigants "raising only a generally available grievance about government," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 573–74 (1992)—"however sharp" their disagreement, *Hollingsworth v. Perry*,

570 U.S. 693, 704 (2013)—do not properly invoke Article III jurisdiction. Lacking any cognizable injury traceable to the challenged conduct, Plaintiffs are not proper litigants.

Second, "[i]t is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction." *United States v. Mitchell*, 463 U.S. 206, 212 (1983). Accordingly, "[a]bsent a waiver, sovereign immunity shields the Federal Government and its agencies from suit." *FDIC v. Meyer*, 510 U.S. 471, 475 (1994). Plaintiffs' claims are not covered by a requisite waiver.

A. No Plaintiff has standing

The standing "doctrine limits the category of litigants empowered to maintain a lawsuit in federal court" only to those who "have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *see Lujan*, 504 U.S. at 560–61. This "triad of injury in fact, causation, and redressability constitutes the core of Article III's case-or-controversy requirement." *Steel Co.*, 523 U.S. at 103–04. Because "standing is not dispensed in gross," Plaintiffs "must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion*, 141 S. Ct. at 2208. None of the Plaintiffs has standing.

1. With no actual or imminent injury to themselves or their children, the individual plaintiffs lack standing

The five individual plaintiffs, *see* Am. Compl. ¶¶ 9–12, must establish an injury-in-fact "that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 578 U.S. at 339 (quoting *Lujan*, 504 U.S. at 560). The individuals all aver an "imminent risk" of harm to their children from the Pfizer and Moderna EUAs. Am. Compl. ¶¶ 9–12.[2] "For a threatened future injury to satisfy the imminence

[2] Plaintiffs also cursorily allege that their children have been exposed to so-called "pro vaccine messaging," Am. Compl. ¶ 96, but "the purported indignity of receiving a"

requirement, there must be at least a 'substantial risk' that the injury will occur." *Stringer v. Whitley*, 942 F.3d 715, 721 (5th Cir. 2019). "[A]llegations of possible future injury are not sufficient," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013), because they are "too speculative for Article III purposes," *Stringer*, 942 F.3d at 721 (quotations omitted). That is the situation here.

As an initial matter, "FDA does not mandate vaccines for the general public." ECF No. 26-1, at 97; *accord Children's Health Def.*, 2022 WL 2704554, at *4 ("FDA has not required the general public to be vaccinated."). Consistent with that broad proposition and the specific statutory authority at issue here, *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), neither EUA compels any individual to receive the vaccine or any parent to consent to administration to their child, *see generally* ECF No. 26-1, at 104–29; ECF No. 26-2, at 77–101. Rather, as the caregiver Fact Sheets expressly state, "there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard of medical care." Pfizer Fact Sheet for 6 Months Through 4 Years, at 5. By simply opting against vaccination, the individual plaintiffs will prevent the future injury they fear from manifesting. In these circumstances—"an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control"—imminence "has been stretched beyond the breaking point." *Lujan*, 504 U.S. at 564 n.2; *see Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) ("In light of plaintiffs' avowed intention to refuse thimerosal-preserved vaccines, plaintiffs cannot show that they face a 'certainly impending,' or even likely, risk of future physical injury from thimerosal in vaccines.").

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message with which one disagrees is "a psychic injury [that] falls well short of a concrete harm needed to establish Article III standing." *Glennborough Homeowners Ass'n v. U.S. Postal Serv.*, 21 F.4th 410, 415 (6th Cir. 2021); *see Hein v. Freedom From Religion Found.*, 551 U.S. 587, 634 (2007) (Scalia, J., concurring) ("mental angst" generally not a cognizable injury).

But even setting aside the lack of imminent injury traceable to the EUAs, the individual plaintiffs do not plead an impending injury from any source. Deborah Else and Sacha Dietrich live with their children in Texas. Am. Compl. ¶¶ 9–10. Texas law affords them the right to consent, or "not to consent," to their children's medical care, including whether to receive an EUA vaccine. *Miller ex rel. Miller v. HCA, Inc.*, 118 S.W.3d 758, 766 (Tex. 2003); *see* Tex. Fam. Code § 151.001(6). They do not deny this right to "make medical decisions" for their children, Am. Compl. ¶ 99, rendering irrelevant all allegations about the Department of Family and Protective Service's Permanent Managing Conservatorship program, *see id.* ¶¶ 99–111.

Else and Dietrich fear that "any consenting adult" might authorize immunization of their children "against the[ir] wishes and consent" or "without their . . . knowledge." *Id.* ¶¶ 115–16. But the law they cite precludes that possibility if the parent is "available" or when the parent "has expressly refused to give consent to the immunization." Tex. Fam. Code § 32.101(b)–(c); *see* Am. Compl. ¶ 112 & n.5. Else and Dietrich also fail to "clearly allege" any "facts" showing that the event they fear—future immunization of their children due to an unknown third-party's actions and over their objection—is imminent. *Spokeo*, 578 U.S. at 338. Absent that, their "unadorned speculation will not suffice" for standing. *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 44 (1976).

To contrive an imminent risk that her children will be vaccinated, Dietrich next invokes the specter of social "pressure" and "impending mandates." Am. Compl. ¶ 10. (Else more realistically describes them as "recommendations." *Id.* ¶ 128.) But any risk of vaccination over their objection was eliminated when the governor prohibited any "entity in Texas" from "compel[ing] receipt of a COVID-19 vaccine by any individual, . . . who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons," Executive Order GA-40 (Oct. 11, 2021); *see* Tex. Gov't Code § 418.012 ("Executive orders . . . have the force and effect of law."); *see also Tenth St. Residential Ass'n v. City of Dall.*, 968 F.3d 492, 501 (5th Cir. 2020) (no standing

when city ordinance prohibited funding the feared demolition of homes). The Amended Complaint generally avers that Texas children are "being denied medical services" due to lack of vaccination, Am. Compl. ¶ 119, yet again offers no facts demonstrating that Else and Dietrich's children will imminently be denied medical services, *see Spokeo*, 578 U.S. at 339 ("a plaintiff must show that *he or she*" will suffer the requisite injury in fact) (emphasis added). The only story they cite covers a single instance and declares that the hospital in question "*Denies* Requiring COVID-19 Vaccine for Organ Transplant Patients." Am. Compl. ¶ 119 n.55 (emphasis added). At bottom, the "remote possibility of harm" to Else and Dietrich's children "fails [standing's] imminence requirement." *Tenth Street*, 968 F.3d at 501.

The next individual plaintiff, Amy Villella, lives with her children in Florida. Am. Compl. ¶ 11.[3] Florida law prohibits "an educational institution or elected or appointed local official" from "impos[ing] a COVID-19 vaccination mandate for any student." Fla. Stat. § 381.00319. Plaintiffs further acknowledge that Florida's Department of Health "recommend[s] *against* healthy children" aged 17 and younger receiving a COVID-19 vaccine. Am. Compl. ¶ 82 (emphasis added). Against this backdrop, Villella does not "clearly allege facts" as she must, *Spokeo*, 578 U.S. at 338 (cleaned up), to render plausible her conclusory claim of an "imminent risk of harm" from the EUAs' issuance, Am. Compl ¶ 11. Like Else and Dietrich, Villella offers nothing but "unadorned speculation" as a basis for standing. *Simon*, 426 U.S. at 44.

So too for the last individual plaintiffs, Jonathan and Rebecca Shour, who reside with their children in North Carolina. Am. Compl. ¶ 12. That state prohibits a health care provider from "administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age"—which would include the

[3] She also claims to reside in North Carolina, *id.* ¶ 131, but the outcome is no different.

Pfizer and Moderna EUAs— without previously "obtaining written consent from a parent or legal guardian." N.C. Gen. Stat. § 90-21.5(a1). Guaranteed the right to withhold consent for the EUA vaccines in North Carolina, the Shours hypothesize that they might be "relocated around the country" for work *and* that unknown state might have a vaccine mandate for children *and* that unknown mandate in that unknown state might not accommodate "their religious objections to the COVID-19 vaccine." Am. Compl. ¶ 130. Relying on a triple layer of conjecture to create an "imminent risk from FDA's EUA[s]," Am. Compl. ¶ 12, is far "too speculative for Article III purposes," *Stringer*, 942 F.3d at 721 (quotation omitted).

Even if a cognizable injury materialized for any individual, it would be traceable to the "decisions of independent actors," *not* FDA's mere issuance of the Pfizer and Moderna EUAs. *Clapper*, 568 U.S. at 414; *see Children's Health Def.*, 2022 WL 2704554, at *3–4 (any alleged injuries from vaccine mandates are "not fairly traceable to FDA's actions" in authorizing the Pfizer COVID-19 vaccine); *Null v. FDA*, No. CV 09-1924 (RBW), 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009). The challenged EUAs, again, compel no action whatsoever from any parent or child. Thus, any injury derived from the independent actions of third parties—from the unknown persons who Else and Dietrich worry might consent to vaccinate their children to the hypothetical state authorities who set vaccination policies disagreeable to the Shours—could not support standing against the defendants here. *See, e.g.*, *Clapper*, 568 U.S. at 414.

Ultimately, the individual plaintiffs have not borne "the burden of pleading . . . concrete facts showing that [FDA's] actual action has caused the substantial risk of harm." *Clapper*, 568 U.S. at 414 n.5. The fear that their children might receive an EUA vaccine over their objection "is not supported by any facts" and is "purely speculative." *Crane v. Johnson*, 783 F.3d 244, 252 (5th Cir. 2015). Accordingly, they lack standing and "may not litigate as suitors in the courts of the United States." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 475–76 (1982).

2. CHD lacks associational and organizational standing

CHD asserts both associational standing, on behalf of its members, and organizational standing, on its own behalf. Am. Compl. ¶ 8; *NAACP v. City of Kyle*, 626 F.3d 233, 237–38 (5th Cir. 2010). It has neither.

Associational standing requires that one of CHD's members "independently" possess Article III standing. *Ctr. for Biological Diversity v. U.S. EPA*, 937 F.3d 533, 536 (5th Cir. 2019). Among other things, CHD must "make specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009). The only identified CHD members—Else, Dietrich, and the Shours[4]—lack standing. Thus, CHD lacks associational standing. *See, e.g.*, *City of Kyle*, 626 F.3d at 237 (rejecting "NAACP's associational-standing claim" given "no evidence in the record showing that a specific member of the NAACP" had standing).

Organizational standing requires that CHD exhibit a "concrete and demonstrable injury to [its] activities—with the consequent drain on [its] resources," not "simply a setback to [its] abstract social interests." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). CHD first alleges that "FDA's conduct toward children . . . caused a serious diversion of the organization's resources from its mission to correct this critical error and try to protect the members and mission of CHD." Am. Compl. ¶ 8. "However, an organization does not automatically suffer a cognizable injury in fact by diverting resources in response to a defendant's conduct." *El Paso Cnty. v. Trump*, 982 F.3d 332, 343–44 (5th Cir. 2020). Only a "diversion of resources" that "concretely and 'perceptibly impaired' [CHD's] ability to carry out its purpose" suffices for standing. *City of Kyle*, 626 F.3d at 239 (quoting *Havens Realty*, 455 U.S. at 379).

A "vague, conclusory assertion" that CHD "had to divert resources is insufficient to establish" a perceptible impairment of CHD's mission. *El Paso*, 982 F.3d at 344. Yet

[4] Villella is a CHD "employee," not a member. Am. Compl. ¶ 11. Regardless, she too lacks standing and cannot support CHD's associational standing.

the Amended Complaint offers nothing more than that, *see* Am. Compl. ¶ 162, failing to "clearly allege facts" that support standing, *Spokeo*, 578 U.S. at 338 (cleaned up). Tellingly, CHD has not "identified any specific projects" it "had to put on hold or otherwise curtail in order to respond to the" EUAs. *City of Kyle*, 626 F.3d at 238; *see, e.g.*, *El Paso*, 982 F.3d at 344–45 (organization lacked standing because it "does not identify any particular projects that suffered because of the diversion of resources").

CHD lists several actions taken in response to or anticipation of the EUAs, including filing a Citizen Petition with FDA, discussing its views with members, and engaging in public outreach. *See* Am. Compl. ¶¶ 156–59. But CHD "has tasked itself with protecting and promoting the health and wellbeing of children." Am. Compl. ¶ 162. So none of these undertakings "detract or 'differ from its routine [] activities.'" *Tenth Street*, 968 F.3d at 500 (quoting *City of Kyle*, 626 F.3d at 238); *see Clark v. Edwards*, 468 F. Supp. 3d 725, 746–47 (M.D. La. 2020) (finding no "significant diversion of resources" when the alleged injury "seems consistent with [the organizations'] general activities and mission"). Apart from the costs of bringing this suit—which do not "satisfy the injury-in-fact requirement," *Williams v. Parker*, 843 F.3d 617, 621 (5th Cir. 2016)—the Amended Complaint contains "only conjecture[] that the resources" CHD devoted to addressing the EUAs "could have been spent on other unspecified . . . activities," *City of Kyle*, 626 F.3d at 239. Because CHD's claim of resource diversion and mission impairment "is not supported by any facts," the alleged "injury is purely speculative" and does not "establish standing." *Crane*, 783 F.3d at 252.

CHD also advances a procedural-injury theory, citing denial of "its right to petition, the chance at notice-and-comment, and its procedural remedies under the" APA. Am. Compl. ¶ 162. Beyond the underlying flaws with these allegations, *see infra* pages 17–18, a "bare procedural violation, divorced from any concrete harm," cannot "satisfy the injury-in-fact requirement of Article III," *Spokeo*, 578 U.S. at 341; *see Summers*, 555 U.S. at 496. That is, CHD still "must show an injury that is both concrete

and particular, as opposed to an undifferentiated interest in the proper application of the law." *Sierra Club v. Glickman*, 156 F.3d 606, 613 (5th Cir. 1998). Its claimed "inability to comment effectively or fully" on the EUAs could not, by itself, establish standing. *Defs. of Wildlife v. Perciasepe*, 714 F.3d 1317, 1325 (D.C. Cir. 2013). The only other hint of concrete, organizational harm is the inadequate allegation of diverted resources. Thus, because CHD's "claimed procedural injury does not impact any concrete interest," it lacks standing to challenge the purported denial of its petition and APA procedural rights. *City of Hearne v. Johnson*, 929 F.3d 298, 302 (5th Cir. 2019); *see Shrimpers & Fishermen of RGV v. Tex. Comm'n on Env't Quality*, 968 F.3d 419, 425–26 (5th Cir. 2020). When no plaintiff has standing, the Court "announc[es] the fact and dismiss[es] the cause." *Ex parte McCardle*, 74 U.S. 506, 514 (1868).

B. Sovereign immunity bars Plaintiffs' causes of action

Even if Plaintiffs had standing, "[t]o bring a claim against a sovereign," Plaintiffs also must show the "sovereign has waived its immunity from suit." *Walmart Inc. v. U.S. Dep't of Just.*, 21 F.4th 300, 307 (5th Cir. 2021). Such a waiver is "strictly construed, in terms of its scope, in favor of the sovereign." *Dep't of Army v. Blue Fox, Inc.*, 525 U.S. 255, 261 (1999). The APA, 5 U.S.C. § 702, is Plaintiffs' only potential source of a waiver. *See* Am. Compl. ¶¶ 15, 215.[5] But the APA's waiver is not absolute.

The APA does not apply when "statutes preclude judicial review" or when "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(1)–(2); *see Webster v. Doe*, 486 U.S. 592, 599 (1988); *Stockman v. Fed. Election Comm'n*, 138 F.3d 144,

[5] Neither 28 U.S.C. § 1331 nor 28 U.S.C. § 2201, *see* Am. Compl. ¶¶ 16, 250, waives sovereign immunity, *see Koehler v. United States*, 153 F.3d 263, 266 n.2 (5th Cir. 1998); *Gaar v. Quirk*, 86 F.3d 451, 453 (5th Cir. 1996). Plaintiffs also cite the mandamus statute, 28 U.S.C. § 1361, but plead no mandamus claim, *see* Am. Compl. ¶ 16. Regardless, because Plaintiffs do not demand FDA "perform a ministerial duty imposed on it by law" but instead seek to require FDA to "alter its decision on the merits of their claims," they exceed "the function of mandamus" and any waiver of sovereign immunity in that statute. *Drake v. Panama Canal Comm'n*, 907 F.2d 532, 534–35 (5th Cir. 1990).

152 (5th Cir. 1998). For 5 U.S.C. § 701(a)(1), the Court examines whether "a particular statute precludes judicial review" by "its express language, . . . the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984). If "the congressional intent to preclude judicial review is 'fairly discernible in the statutory scheme,'" *Drake*, 907 F.2d at 535 (quoting *Block*, 467 U.S. at 351), section 701(a)(1) applies. Alternatively, 5 U.S.C. § 701(a)(2) looks to the relevant statutory "language" and "structure" to ask if "its implementation was 'committed to agency discretion by law.'" *Webster*, 486 U.S. at 600. Given the analytical overlap, section 701(a)(1) and (a)(2) may both support exemption from the APA's sovereign immunity waiver. *See Haitian Refugee Ctr., Inc. v. Baker*, 953 F.2d 1498, 1507–08 (11th Cir. 1992).

The Pfizer and Moderna EUAs were expressly issued "pursuant to" 21 U.S.C. § 360bbb-3. ECF No. 26-1, at 104–07, 115–16; ECF No. 26-2, at 77–80, 87–88. And 21 U.S.C. § 360bbb-3(i) states that "[a]ctions under the authority of this section by the Secretary . . . are committed to agency discretion." That language tracks section 701(a)(2)'s exception to APA review when "agency action is committed to agency discretion by law." Because the language of 21 U.S.C. § 360bbb-3(i) "is plain," the Court must enforce the statute "according to its terms." *Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) (quotations omitted). Indeed, the Sixth Circuit concluded this language means that EUAs "are exempt from review under the APA." *Ass'n of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (citing 5 U.S.C. § 701(a)(2)).

The Sixth Circuit's conclusion is bolstered by the "basic interpretive canon[]" that "a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (cleaned up). Apart from committing actions to agency discretion, 21 U.S.C. § 360bbb-3(i) contains no other language. Thus, it functionally serves no other

purpose than summoning the APA's exemption in 5 U.S.C. § 701(a). A failure to apply the exemption would impermissibly render 21 U.S.C. § 360bbb-3(i) meaningless.

Although the statute's plain meaning is dispositive, its purpose and structure confirm that FDA's issuance of the EUAs is "unreviewable" under section 701(a). *FDIC v. Bank of Coushatta*, 930 F.2d 1122, 1129 (5th Cir. 1991); *see Webster*, 486 U.S. at 600–01. The EUA statute was largely enacted as part of the Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, which granted FDA authority to issue EUAs to "streamlin[e] . . . the approval process of countermeasures" against chemical, biological, radiological, or nuclear agents that might be used against the United States. And agency discretion permeates the authorization process. For example, the Secretary "may" declare "that the circumstances exist justifying" an EUA, 21 U.S.C. § 360bbb-3(b)(1); "may" issue an EUA, *id.* § 360bbb-3(a)(1), (c); "may" impose conditions that are "necessary and appropriate to protect the public health," *id.* § 360bbb-3(e)(1)(B); and "may revise or revoke" an EUA, *id.* § 360bbb-3(g)(2); *see Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016) ("the word 'may' . . . implies discretion"). Indeed, even when the statute directs the agency to establish conditions on EUA products, it includes discretionary caveats. *See* 21 U.S.C. § 360bbb-3(e)(1)(A) ("to the extent practicable given the applicable circumstances" and "such conditions . . . as the Secretary finds necessary or appropriate to protect the public health").

Thus, through the language, structure, and purpose of 21 U.S.C. § 360bbb-3, Congress's intent to preclude judicial review of FDA's decision to issue EUAs under 5 U.S.C. § 701(a)(1) is "fairly discernible." *Drake*, 907 F.2d at 535. Alternatively, because the "language and structure" of 21 U.S.C. § 360bbb-3 "fairly exudes deference to" FDA, 5 U.S.C. § 701(a)(2) "precludes judicial review of [these] decision[s] under the APA." *Webster*, 486 U.S. at 600–01; *see Bank of Coushatta*, 930 F.2d at 1129. Either way, the result is the same: no waiver of sovereign immunity and no subject-matter jurisdiction.

II. Even if this Court has jurisdiction, Plaintiffs' claims are implausible

Even if Plaintiffs could establish this Court's jurisdiction, their suit still should be dismissed for failure to plausibly state a claim for relief. "Rule 12(b)(6) requires dismissal whenever a plaintiff's claim is based on an invalid legal theory." *Residents Against Flooding v. Reinvestment Zone No. Seventeen*, 260 F. Supp. 3d 738, 803 (S.D. Tex. 2017); *see Neitzke*, 490 U.S. at 326–27. Dismissal also is required when the facts pleaded in the complaint do not "plausibly support each element" of the alleged cause of action. *Pena v. City of Rio Grande City*, 879 F.3d 613, 621 (5th Cir. 2018).

"To state a proper claim under the APA," Plaintiffs "must allege facts that, if true, plausibly establish that the agency action is arbitrary and capricious." *Blanchett v. DeVos*, 490 F. Supp. 3d 26, 32 (D.D.C. 2020); *see, e.g.*, *Palacios v. Dep't of Homeland Sec.*, 434 F. Supp. 3d 500, 506 (S.D. Tex. 2020). "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Review also is "at its most deferential" because the case involves "scientific determination[s]" and "predictions" by FDA "within its area of special expertise." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council*, 462 U.S. 87, 103 (1983).

None of Plaintiffs' numerous arguments amounts to a plausible APA claim. *First*, Plaintiffs contend that "FDA failed to justify its conclusion that children ages 6 months through 11 years face an emergency" to support "an EUA declaration." Am. Compl. ¶¶ 218–19 (citing 21 U.S.C. § 360bbb-3(b)(1)). But that muddles the legal criteria and neglects the agency's public reasoning. Under 21 U.S.C. § 360bbb-3(b)(1), the Secretary "may make a declaration that the circumstances exist justifying" an emergency authorization "for a product." The Secretary did so, determining that a public health emergency exists involving the virus "SARS–CoV–2, which causes the illness COVID–19," and that "circumstances exist justifying the authorization of emergency use of . . .

biological products during the COVID–19 pandemic." 85 Fed. Reg. at 18,250–51. This declaration thus resolved whether a public-health emergency exists.

FDA then may issue an EUA for a specific product if it concludes certain criteria are met, as the agency did here. *See* 21 U.S.C. § 360bbb-3(c) (setting forth criteria). FDA found that "SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness [*i.e.*, COVID-19], to humans infected by this virus." ECF No. 26-1, at 115; ECF No. 26-2, at 87; *see* 21 U.S.C. § 360bbb-3(c)(1). Data about the consequences of COVID-19 include "COVID-19-associated hospitalizations and deaths [that] have occurred in children," as well as symptoms that linger "for weeks to months after the[] initial illness." ECF No. 26-2, at 9. The agency further found that the Pfizer and Moderna EUA vaccines "may be effective in preventing COVID-19, and that, when used under the conditions" of authorization, "the known and potential benefits of" the EUA vaccines "when used to prevent COVID-19 outweigh [the] known and potential risks." ECF No. 26-1, at 115; ECF No. 26-2, at 87; *see* 21 U.S.C. § 360bbb-3(c)(2); ECF No. 26-2, at 64–69 (analyzing risks and benefits). Thus, FDA's public explanations belie any plausible claim that the agency did not justify its conclusions.

Second, Plaintiffs aver that FDA "denied CHD its procedural right to seek redress via citizen petition, a right conforming to the right to petition under the First Amendment." Am. Compl. ¶ 224. The First Amendment's "Petition Clause protects the right of individuals to appeal to courts and other forums established by the government for resolution of legal disputes." *Borough of Duryea v. Guarnieri*, 564 U.S. 379, 387 (2011). "CHD *exercised that right* by filing a citizen petition," Am. Compl. ¶ 226 (emphasis added), to which FDA responded, in great detail, a few months later, *see* ECF No. 26-3, at 62–114. Although FDA disagreed with CHD, "[t]he First Amendment does not mandate a result once such petitions are received." *City of Hearne*, 929 F.3d at 301.

Third, Plaintiffs believe that "FDA and CDC have altered the traditional definitions of 'vaccine' and 'vaccination' to encompass the COVID-19 biologics," supposedly "in

violation of procedural due process." Am. Compl. ¶ 230. Plaintiffs must "point to some" interest protected by the due process clause, but they do not and thus fail "to state a due process claim." *Gentilello v. Rege*, 627 F.3d 540, 545 (5th Cir. 2010). Even if they had, deprivation of a protected interest "is not in itself unconstitutional; what is unconstitutional is the deprivation of such an interest *without due process of law*." *Zinermon v. Burch*, 494 U.S. 113, 125 (1990). Plaintiffs allege a denial of "a citizen participation or notice-and-comment process when [FDA] labeled the COVID-19 biologics as vaccines." Am. Compl. ¶ 231. Yet Plaintiffs undeniably availed themselves of FDA's petition process to submit their views and request "administrative action." 21 C.F.R. § 10.25(a); *see* ECF No. 26-3, at 42–114. Further, notice-and-comment is *not* required by the statutes governing issuance of EUAs, 21 U.S.C. § 360bbb-3(c)–(d), and approval of biological products like vaccines, 42 U.S.C. § 262(a).

As for the supposedly altered definitions, the only specific definitions cited in the Complaint are from a CDC informational webpage and The Free Dictionary online. Am. Compl. ¶¶ 135–36. No factual allegations show FDA's responsibility for this Internet content. *See Iqbal*, 556 U.S. at 678. Moreover, neither the CDC webpage nor The Free Dictionary qualifies as a "substantive rule," with "the force of law," that triggers notice-and-comment under 5 U.S.C. § 553(b). *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995); *see Lincoln v. Virgil*, 508 U.S. 182, 196 (1993).

Fourth, Plaintiffs argue that FDA's consideration and explanation of several issues was inadequate. *See* Am. Compl. ¶¶ 233–43. But each alleged deficiency is refuted by agency documents, which undercut any plausible allegation that FDA "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

- Plaintiffs allege "FDA failed to articulate any standard for assessing an individualized, stratified risk for children between the ages of 6 months and

11 years," and its risk assessment methodology "is still shrouded in mystery." Am. Compl. ¶¶ 234, 236. However, "[a]gencies are not required to proceed by set standards in order to avoid a finding that their actions are arbitrary and capricious," *Hayward v. U.S. Dep't of Labor*, 536 F.3d 376, 382 (5th Cir. 2008), so FDA was not "obligat[ed] to create such a standard" in the first instance, Am Compl. ¶ 234. Regardless, the agency fully explained its risk assessment and methodology. *See* ECF No. 26-2, at 62–67.

- Plaintiffs allege FDA "failed to address the inadequacies regarding clinical trials," including "adverse events." Am. Compl. ¶ 239. In fact, the agency scrutinized the trials' results and safety in depth. *See* ECF No. 26-2, at 18–59.

- Plaintiffs allege "FDA ignored data on the high recovery rate of children diagnosed with COVID-19 and the high rates of natural immunity." Am. Compl. ¶ 240. Actually, FDA noted both that "[m]ost children with COVID-19 recovered within 1 to 2 weeks" and that COVID-19 vaccine data "have demonstrated an added benefit of vaccination to protection conferred by natural immunity." ECF No. 26-2, at 9, 65.

- Plaintiffs allege FDA "ignored adverse events that have been documented through the [Vaccine Adverse Events Reporting System] database." Am. Compl. ¶ 241. On the contrary, FDA "queried" that database for adverse event "reports following the Pfizer-BioNTech COVID-19 Vaccine," and analyzed the results. ECF No. 26-2, at 13-14.

- Plaintiffs allege FDA should not have granted EUAs under 21 U.S.C. § 360bbb-3(c)(3) because there are alternative treatments available, and FDA "dismissed the effectiveness of alternative treatments." Am. Compl. ¶ 242. But Plaintiffs concede these "alternative treatments" have not "been recognized," *i.e.* approved, by FDA for the prevention or treatment of COVID-19. *Id.* And only products that have been "approved, licensed, or cleared by FDA," on an "indication-specific" basis, qualify under 21 U.S.C. § 360bbb-3(c)(3). ECF No. 26-2, at 90 & n.82.

Fifth, Plaintiffs seek to introduce new arguments from a news article about "allegations of fraud in Pfizer's clinical trials" and whether "mRNA COVID-19 vaccines" are "gene therapies." Am. Compl. ¶¶ 235, 237. But the long-standing rule of "issue exhaustion . . . require[s] parties to give the agency an opportunity to address an issue before seeking judicial review of that question." *Carr v. Saul*, 141 S. Ct. 1352, 1358 (2021); *see United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952). Indeed,

FDA regulations require that any challenger "who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action." 21 C.F.R. § 10.45(f); *see id.* §§ 10.25, 10.30; *see also Carr*, 141 S. Ct. at 1358 ("issue-exhaustion rules" may be "creatures of . . . regulation"). Plaintiffs eschewed that process to present these new issues. Nor have they plausibly alleged that these issues were part of the "administrative record" for the challenged actions. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019).

Because a "federal court reviewing an agency determination will not ordinarily consider arguments that a litigant could have raised before the agency but chose not to," Plaintiffs have waived the issues. *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321, 327–28 (5th Cir. 2020); *see Delta Found., Inc. v. United States*, 303 F.3d 551, 562–63 (5th Cir. 2002) ("disregard[ing]" arguments not previously raised "at the administrative level"). And these new arguments cannot comprise a plausible APA claim. *See Fleming v. U.S. Dep't of Agric.*, 987 F.3d 1093, 1100 (D.C. Cir. 2021) (court "could not conclude that" an agency decision "was arbitrary and capricious in failing to identify, raise, and resolve *sua sponte* an issue never presented"); *Velez-Duenas v. Swacina*, 875 F. Supp. 2d 1372, 1379 (S.D. Fla. 2012).[6] Without a plausible APA claim, Plaintiffs cannot proceed solely under the Declaratory Judgment Act, *see* Am. Compl. ¶¶ 249–50, which does not "provide an independent basis for federal court review." *Offiiong v. Holder*, 864 F. Supp. 2d 611, 626–27 (S.D. Tex. 2012); *see Gaar*, 86 F.3d at 453.

CONCLUSION

For the foregoing reasons, the Court should dismiss this case for lack of subject-matter jurisdiction and failure to state a claim upon which relief can be granted.

[6] Even if preserved, these arguments could not resuscitate the APA claim. For example, although alleging that FDA failed to meet standards for regulating gene therapy products, Am. Compl. ¶ 143, Plaintiffs do not identify any specific standard that FDA failed to apply, *see Iqbal*, 556 U.S. at 678–79 ("legal conclusions" are not presumed true).

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